

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Docket No. 400188)

In re the Application of:)	
)	
DOMINGUEZ ET AL.)	
)	Art Unit: 3763
Serial No.: 10/681,602)	
)	
Filed: October 8, 2003)	Examiner
)	
For: DELIVERY SYSTEM USING BALLOON)	
SYSTEM)	


DECLARATION OF INVENTORS UNDER 37 C.F.R. §1.131

We, Eric Cheng, Susana M. Deutsch, Larry Dominguez and Ajay K. Wakhloo,
declare as follows:

1. We are the named inventors in the above identified application.
2. The subject matter of claim 1-10, a copy of which is attached hereto as Exhibit 1, was conceived prior to December 7, 2000.
3. Attached as Exhibit 2 is an invention record prepared prior to December 7, 2000. The invention was referred to as IR 00/187. Although the dates have been redacted, all of the dates set forth in the invention record are prior to December 7, 2000. The invention record of Exhibit 2 was submitted to patent counsel for Cordis Corporation prior to December 7, 2000.
4. It is believed that the description on page 2 of the invention record of Exhibit 2, together with the two sheets of drawings in the invention record, support the subject matter of claims 1-10 of the above identified application.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Feb 5, 2004
Date


Eric Cheng

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2-5-04

Date

Susana M. Deutsch

Susana M. Deutsch

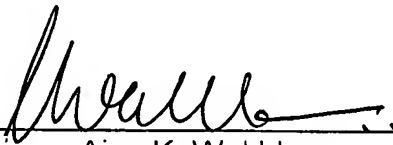
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

01-27-2004
Date

Larry Dominguez
Larry Dominguez

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2/26/04
Date


Ajay K. Wakhloo

It can be seen that a novel system has been disclosed in which an embolic coil is securely placed within an aneurysm with a catheter that is stabilized and is relatively simple in construction and easy to use. Although an illustrative embodiment of the invention has been shown and described, it is to be understood that various modifications and substitutions may be made by those skilled in the art without departing from the novel spirit and scope of the present invention. For example, as stated above an additional port could be used in communication with the balloon to purge air trapped in the balloon and body. Instead of a single lumen used for both the guidewire and the embolic coil delivery device, a guidewire lumen which communicates with the guidewire opening at the distal end and a separate delivery lumen which communicates with the side opening could be utilized. Further, in addition to the delivery of embolics, the system can be utilized to delivery guidewires, diagnostics and therapeutic agents via a delivery lumen. The multiple lumen body may be composed of polymers and/or metals and a balloon may be preformed and attached to the inflation lumen adjacent the distal end of the catheter or formed from the inflation lumen of the multiple lumen body. Other modifications may be made which fall within the scope of the following claims.

What is claimed:

1. A method for placing an embolic coil at a location within an aneurysm comprising the steps of:
providing a catheter having a proximal end and a distal end, a balloon adjacent to the distal end, and an inflation port at the proximal end

communicating via an inflation lumen with the balloon, a guidewire opening at the distal end and a spaced, side opening adjacent the distal end;

introducing the catheter into the vessel of a patient via a guidewire extending through the guidewire opening to generally align the side opening with the aneurysm;

inflating the balloon to stabilize the position of the catheter;

introducing an embolic coil deployment device from the proximal end of the catheter and through the side opening to deliver an embolic coil into the aneurysm;

deflating the balloon; and

thereafter withdrawing the catheter from the patient's vessel.

2. A method for placing an embolic coil at a location within an aneurysm comprising the steps of:

providing a catheter having a proximal end and a distal end, a balloon adjacent the distal end, an inflation port at the proximal end communicating via an inflation lumen with the balloon, a delivery port at the proximal end communicating with a delivery lumen, a guidewire opening at the distal end communicating with the delivery lumen, and a side opening adjacent the distal end also communicating with the delivery lumen;

preloading the catheter with a guidewire extending from the delivery port through the delivery lumen and distal of the guidewire opening;

thereafter introducing the catheter into the vessel of a patient to generally align the side opening with the aneurysm;

inflating the balloon to stabilize the position of the catheter;

thereafter, withdrawing the guidewire and introducing an embolic coil deployment device into the delivery lumen and through the side opening to deliver an embolic coil into the aneurysm;

5 deflating the balloon; and

thereafter withdrawing the catheter from the patient's vessel.

3. A method for placing a medical agent at a location within a patient's vessel, comprising the steps of:

10 providing a catheter having a proximal end and a distal end, a balloon adjacent to the distal end, an inflation port at the proximal end communicating via an inflation lumen with the balloon, a delivery port at the proximal end communicating with a delivery lumen, a guidewire opening at the distal end communicating with the delivery lumen, and a side opening adjacent to the distal end also communicating with the delivery lumen;

15 preloading the catheter with a guidewire extending from the delivery port through the delivery lumen and distal of the guidewire opening;

thereafter introducing the catheter into the vessel of a patient to generally align the side opening with the location to be treated;

inflating the balloon to stabilize the position of the catheter;

20 thereafter withdrawing the guidewire and introducing the medical agent into the delivery lumen and through the side opening whereby it is placed in the location to be treated;

deflating the balloon; and

thereafter withdrawing the catheter from the patient's vessel.

4. A method as defined in claim 3, in which said medical agent comprises an embolic coil.

5. A method as defined in claim 3, in which said medical agent comprises a therapeutic agent.

5 6. A method as defined in claim 3, in which said medical agent comprises medicament.

7. A method as defined in claim 3, in which said medical agent comprises a diagnostic agent.

10 8. A method as defined in claim 3, in which said medical agent comprises an embolic agent.

9. A method as defined in claim 8, in which said embolic agent is selected from the group consisting of liquid embolic agents, biocompatible polymer-solvent combinations, biocompatible polymers and other embolizing compositions.

10. A balloon catheter which comprises:
15 a catheter body having a proximal end and a distal end;
a balloon adjacent the distal end;
an inflation port at the proximal end;
the catheter body defining an inflation lumen;
said inflation port communicating via the inflation lumen with the balloon;
20 a delivery port at the proximal end;
said body defining a delivery lumen separate from said inflation lumen;
a guidewire opening at the distal end communicating with the delivery
lumen;

a side opening adjacent the distal end, spaced from the guidewire opening,
and communicating with the delivery lumen;

said balloon being substantially radially aligned with said side opening
and substantially oppositely positioned on the catheter with respect to the side
opening.

5

Cordis

a Johnson & Johnson company

00/187

DESCRIPTIVE TITLE:

- I. **INSTRUCTIONS:** This form should be typed, except for the signatures and dates. Disclose only one invention on this Invention Disclosure form, and complete the entire form as fully as possible. Forward the completed form to the Legal Department, signed and dated by all inventors and two witnesses. Refer to this Invention Disclosure by the number assigned to it when receipt is acknowledged. Attach additional sheets if more space is required. Each original piece of paper must be signed and dated by every inventor and by each witness.
- II. **ILLUSTRATION:** Include a drawing, sketch, photograph, flow chart, or preferably an engineering quality printout of the invention.

See attached data sheets.

Name & Signature of Inventor(s):

Date

Witnesses

Date

Walter Dominguez

Donald K. Jones

III. **EXPLANATION OF INVENTION:**

The micro-catheter consists of a multiple port hub, a multiple lumen body, and a balloon.

The multiple port hub is attached to the proximal end of the catheter body. At least one port is in fluid communication with the balloon via the inflation lumen. A secondary port may also be in fluid communication with the balloon. The secondary port and lumen would be used to purge air trapped in the balloon and body. A third port would be used to deliver guide wires, embolics, diagnostic, and therapeutic agents via a delivery lumen.

The multiple lumen body is composed of polymers and/or metals and is attached to the multiple port hub at the proximal end and attached to the balloon at the distal end. The balloon is attached to or formed of the distal tip of the dual lumen. The delivery lumen is attached at the proximal end to the delivery port of the hub and exposed at the distal end proximal of the distal tip. This allows for the delivery of embolics, diagnostic, and therapeutic agents via a delivery lumen in a lateral approach as opposed to the traditional distal tip approach.

The balloon is composed of polymers. The balloon may be performed and attached to the inflation lumen at the distal tip of the catheter or formed from the inflation lumen of the multiple lumen body.

IV. **NOVEL FEATURES AND ADVANTAGES:**

The ability to deliver embolic, diagnostic, and/or therapeutic agents in a lateral approach and position the micro catheter via a balloon.

V. **MODIFICATIONS:**

The delivery lumen could be kept intact without a cut. This would allow for the delivery of embolics, diagnostic, and therapeutic agents via the distal tip of the delivery lumen.

VI. **RELATED DOCUMENTS:** *List all known relevant art references (patents, publications, commercially available products, etc.) Please supply copies of the documents, if available.*

Patents:

Publications:

Signature of Inventor(s):

C. M. Deming, et al.

Date:

Witnesses:

Donald K. Jones

Date:

VII. INVENTORS:

First Inventor's Full name (Please type:)

Larry Dominguez

Signature: _____

Date: _____

Second Inventor's Full Name (Please type):

Signature: _____

Date: _____

VIII. WITNESSES: This invention was disclosed to and understood by:

Full Name of First Witness (Please type):

Boris Shkolnik

Signature: _____

Date: _____

Full Name of Second Witness (Please type:)

Don Jones

Signature: _____

Date: _____

IX. ADDITIONAL INFORMATION:

Invention is recorded on page(s): 81-82 of Notebook No.: 91251 dated: _____

Earliest date: _____ and place: Cordis Endovascular Systems where inventors first thought of the present invention.

First written description (date and present location): _____

First sketch of the invention (date and present location): _____ Cordis Endovascular Systems

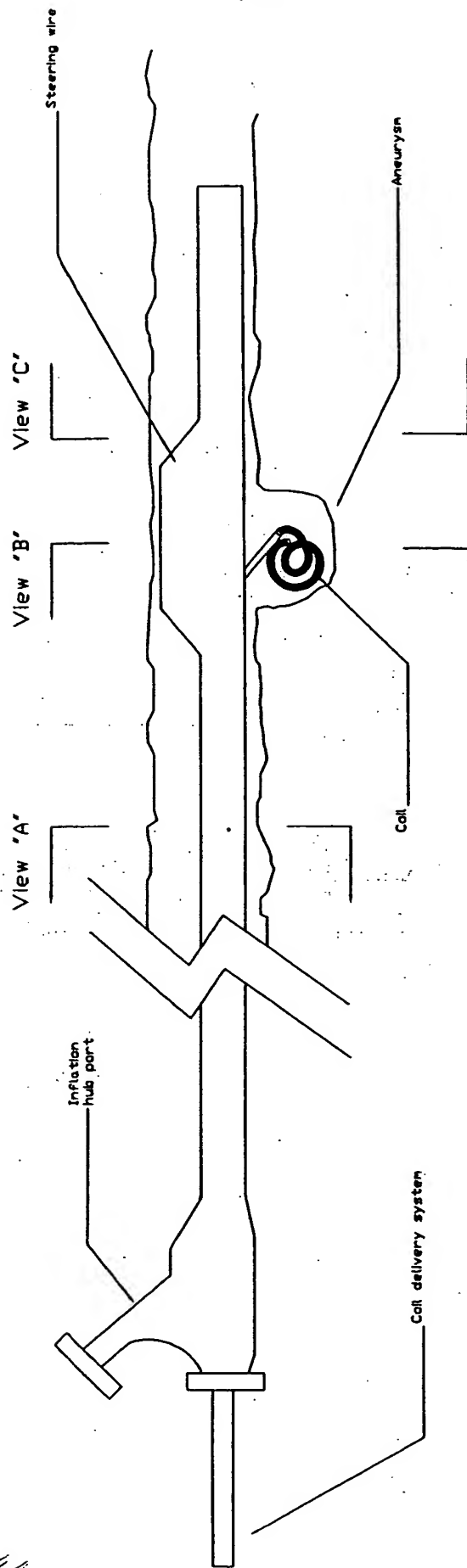
Earliest date: N/A and place: N/A where first operating model was completed.

Present location of model: N/A

Earliest date of use of the invention (actual or contemplated): N/A

Earliest shipping date (actual or contemplated): N/A

Illustration of catheter treating an aneurysm



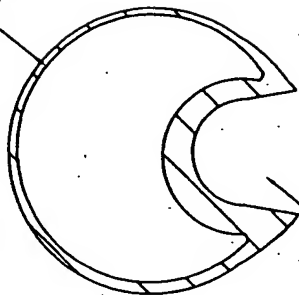
Carry Dominguez

David R. Lee

David R. Lee

Balloon
(Inflated)

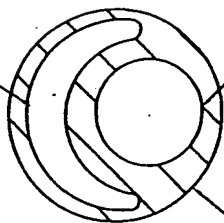
View 'B'



Delivery port

Inflation lumen
(deflated)

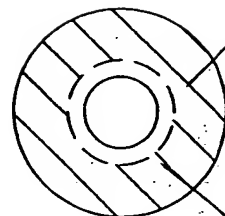
View 'A'



Delivery lumen

Dual lumen
polymer body

View 'C'



Original I.D.

Reduced I.D.

Early Sonogor

Donald K. Jones

James H. H. H.